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Application No.	S2001/0547
Date of Filing	7 June 2001
Applicant	CHRISTY CUMMINS, an Irish Citizen of 54 Knockowen, Tullamore, County Offaly, Ireland.

Dated this 28th day of June 2002.

An officer authorised by the
Controller of Patents, Designs and Trademarks.

FORM NO. 1

S010547

REQUEST FOR THE GRANT OF A PATENT
PATENTS ACT, 1992

The Applicant named herein hereby request

__ the grant of a patent under Part II of the Act

_X_ the grant of a short-term patent under Part III of the Act

on the basis of the information furnished hereunder.

1. **APPLICANT**

Name	**Christy Cummins**
Address	**54 Knockowen, Tullamore, County Offaly, Ireland**
Description/Nationality	**An Irish Citizen**

2. **TITLE OF INVENTION**

"Surgical Staple"

3. **DECLARATION OF PRIORITY ON BASIS OF PREVIOUSLY FILED APPLICATION FOR SAME INVENTION (SECTIONS 25 & 26)**

Previous filing date	Country in or for which filed	Filing No.

4. **IDENTIFICATION OF INVENTOR(S)**
Name(s) of person(s) believed by Applicant(s) to be the inventor(s)
1. Christy Cummins

Address
1. 54 Knockowen, Tullamore, County Offaly, Ireland

5. **STATEMENT OF RIGHT TO BE GRANTED A PATENT (SECTION 17(2)(B))**

By virtue of the Applicant being the Inventor

Contd./...

6. **ITEMS ACCOMPANYING THIS REQUEST - TICK AS APPROPRIATE**

(i) X prescribed filing fee EUR 63.49(£50.00)

(ii) X specification containing a description and claims

___ specification containing a description only

X Drawings referred to in description or claims

(iii) X An abstract

iv) ___ Copy of previous application(s) whose priority is claimed

(v) ___ Translation of previous application whose priority is claimed

(vi) X Authorisation of Agent (this may be given at 8 below if this Request is signed by the Applicant(s))

7. **DIVISIONAL APPLICATION**

The following information is applicable to the present application which is made under Section 24

Earlier Application No:
Filing Date:

8. **AGENT**

The following is authorised to act as agent in all proceedings connected with the obtaining of a Patent to which this request relates and in relation to any patent granted -

Name	**Address**
F. R. KELLY & CO.	at their address as recorded for the time being in the Register of Patent Agents

9. **ADDRESS FOR SERVICE (IF DIFFERENT FROM THAT AT 8)**

CHRISTY CUMMINS
F. R. KELLY & CO.

By: _____
EXECUTIVE

Date: June 7, 2001

Surgical Staple

This invention relates to a surgical staple.

Staples have been used in general surgery for many years, mainly for anastomosing tissue. Examples include skin staplers used to close a skin incision in place of the standard manual suturing process, and end-to-end and end-to-side bowel stapling instruments which are generally one shot devices used during bowel reconstruction procedures.

The staples used with these devices are generally manufactured from a metal or metal alloy material such as stainless steel or titanium. The majority are constructed from round profile wire and generally produced in a generally 'U'-shaped configuration. The ends of the 'U'-shape are normally pointed or sharpened so as to ensure easy tissue penetration. Examples of prior art in this area include US Patents 4,505,273, 5,026,390 and 4,719,917.

In clinical use the staples are delivered using a stapler device which generally consists of an anvil component positioned inside the 'U' between staple legs and in contact with the staple back, the width of the anvil being approximately 60% of the overall width of the staple back. A former component is positioned on the other side of the staple back, the gap between the

forming arms of the former being approximately the width of the anvil plus two times the diameter of the staple wire. The head of the stapler device is normally positioned centrally across the slit or opening which is to be closed.

On activation of the device the staple legs are advanced forward so that they penetrate the tissue on both sides of the slit or opening. As the former is advanced further the arms of the staple bend around the anvil causing the staple legs to bend toward each other so that the staple ultimately assumes a generally rectangular shape thereby compressing the tissue which has been trapped between both staple legs and staple arms. This compression of tissue is the mechanism by which a closure is effected. Depending on the length of the incision or opening a series of staples will be delivered along its length in order to ensure a blood tight closure.

While this method of closing an incision is effective when a series of staples are used along the length of the incision it is less effective when it is desirable to close the opening with the minimum number of staples. For example for an incision of 5-6mm in length one round wire staple positioned centrally along the incision is insufficient to effect a closure as the amount of compression due to the staple arms and legs

will not radiate out to the extremities of the incision.

Also in situations where the tissue is soft and friable the narrow staple leg will have a tendency to tear through the tissue as the staple arms are bent around the anvil thereby decreasing the level of compression between the staple arms and legs and causing unnecessary damage to the vessel wall.

Therefore there is a need for an improved surgical staple which will have the effect of increasing the area of tissue compression between the staple arms and legs upon closure. This will mean that fewer such staples are required to close an incision. In addition it would be advantageous to profile the staple arms and legs so that they are less inclined to tear through softer tissue.

Accordingly, the present invention provides a surgical staple comprising a base and a pair of substantially parallel legs projecting substantially perpendicularly from opposite ends of the base respectively, the base comprising a central portion ("back") and two outer portions ("arms") respectively on opposite sides of the back which in use of the staple are bent through approximately 90^0 relative to the back, the arms having a maximum width, in a direction normal to the plane

containing the legs, greater than the width of the back.

In some embodiments described herein the arms comprise substantially flat portions of the base.

In other embodiments the arms comprise portions of the base bent out of alignment with the back.

The advantage of the invention is that the improved surgical staple delivers a significantly increased area of compression between the staple arms and legs once the staple has been deformed into a generally rectangular shape. The increased area of compression is achieved by increasing the contact area between the staple arms and the tissue against which it is bearing. The contact area between the staple legs may also be increased so as to further increase the area of compression during and following closure.

The invention is particularly useful in applications where the staple is permanently implanted inside the body. In such cases it is desirable to minimise the amount of metal which is needed to effect a positive closure. With existing stapler devices a series of staples need to be positioned along the length of the slit or tissue edges being anastomosed. Staples are normally positioned close together as any one staple will only compress a small amount of tissue on either

side. Using staples with an improved compression capacity, as provided by this invention, will mean that a significantly less number of staples are required to close any one incision.

The invention also has particular relevance in the area of vascular puncture closure. During this percutaneous procedure it is desirable to close the arterial puncture preferably with one staple. Again it is desirable that the staple contains the minimum amount of metal. However, it is important that once delivered the staple has generated enough compression along the length of the slit or hole to prevent any blood leakage.

Embodiments of the invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Fig. 1 is a perspective view of a conventional surgical staple.

Fig. 2a is a sectional view of an unformed staple in a vessel wall.

Fig. 2b is a sectional view of a partially formed staple in a vessel wall.

Fig. 2c is a sectional view of a staple fully formed in a vessel wall.

Fig. 3a is a plan view of a staple before and after forming.

Fig. 3b is an enlarged view of a staple leg before and after forming.

Fig. 4 is a plan view of a staple in position across a tissue opening.

Figs. 5 to 10 are perspective views of embodiments of the invention.

Fig. 11 is a plan view of the staple of Fig. 9 in position across a tissue opening.

In the figures the same reference numerals have been used to indicate the same or equivalent components.

Referring first to Fig. 1, a conventional round wire surgical staple is of a generally 'U'-shaped configuration, consisting of a base 10 and a pair of substantially parallel legs 12 projecting substantially perpendicular from opposite ends of the base. The free ends 14 of the staple legs are generally sharpened so as to ensure easy tissue penetration. In order to transform the staple from a generally 'U'-shape to a

generally rectangular shape during the delivery process, it is necessary to deform the base of the staple by bending the outer portions 10a thereof through 90^0 at points X and Y relative to the central portion 10b, these being known as the bend points. The central base portion 10b between the bend points X and Y is known as the staple back whereas the outer base portions 10a which extend from X and Y respectively towards the junction with the staple legs are known as the staple arms.

Figs. 2(a) to 2(c) are a sequence of views showing the process by which the conventional staple is deployed and deformed from a generally 'U'-shape to a generally rectangular shape to effect a closure of a puncture hole or slit 16 in a vessel or other tissue 18. In Fig. 2a the staple has been advanced from the delivery device (not shown) such that the staple legs 12 have punctured the tissue 18 and the staple back 10b and staple arms 10a are lying against the outer surface of the tissue. In Fig. 2b the forming process has begun and the staple is being deformed around bend points X and Y causing the staple arms 10a and legs 12 to arc through an angle of approximately 90^0 thereby compressing the tissue which is being captured between both staple arms and staple legs. In Fig. 2c the staple has been fully formed into a rectangular shape, the tissue contained within the rectangle being

compressed as a result of the staple arms having arced through approximately 90^0.

In Figs. 3a and 3b, the staple is shown prior to forming (dashed lines) and after forming (solid lines). As seen particularly in Fig. 3b, it can be seen that prior to forming and following penetration of the staple leg 12 into the tissue wall that there is an area of tissue captive in the region (c). After the forming process, i.e. when the staple arm 10a and leg 12 have arced through 90^0 at the bend point Y, the tissue which was previously captive at point (c) has now moved to point (d). The same process of compression occurs on the opposite leg of the staple thereby creating compressed tissue 20 (Fig. 4) within the rectangular shape of the formed staple.

In Fig. 4, the same compression process can be seen in plan view, the tissue which was captive inside the legs 12 at points (c) prior to forming has been moved to point (d) as a result of the staple forming process. However, the level of compression which has transferred to the hole 16 in the tissue is related to the area of surface contact between the staple arm, staple leg and the tissue at points (c) and (d). With conventional round wire staples this contact area is quite small and therefore delivers a limited amount of compression over the length of the hole opening or slit in the tissue. Also, with round wire staples there would be a tendency

for the staple arm and leg to cut its way through softer tissue as opposed to compressing the tissue ahead of it.

The invention solves this problem by increasing the width of the arms 10a, and optionally also the legs 10b, as compared to the back 10a, in order to increase the effective contact area between the staple arms, and optionally also the staple legs, and the tissue as the staple is being deformed from a generally U-shape to a generally rectangular shape. Increasing the contact area in this way will prevent the staple leg and arm from tearing its way through the tissue but more importantly will create a much greater area of compression within the rectangle of the formed staple and radiating from it, so that this compression will be transferred over a much greater length of the slit or opening 16 in the tissue.

Fig. 5 is a perspective view of a first embodiment of surgical staple according to the invention. Here the arms 10a of the conventional round wire staple described above have been deformed from a round to a flat, rectangular cross-section. As mentioned, the purpose of this deformation is to increase the surface contact area between the staple arms and tissue in the direction in which the tissue is being compressed as the staple arm arcs through approximately 900 at its bend points. In the embodiment of Fig. 6 the staple

legs 12 have also been flattened to a generally rectangular cross-section to further increase the area of contact between staple and the tissue being compressed.

Fig. 7 shows another embodiment, in which the staple arms have been divided along the axis of the base section and the opposite divisions 10a' and 10a" deformed apart so as to significantly increase the overall width of the arms.

In Fig. 8 another round wire embodiment of the staple is shown. In this staple the wire in the arms 10a is bent sinusoidally out of alignment with the back 10b such that the staple arms are significantly wider than either the staple back 10b or staple legs 12, again for the purpose of increasing the area of compression.

Fig. 9 shows an embodiment which consists of a standard round wire staple with flat plates or wings 22 attached to the base 10 on either side of the back 10b. Fig. 10 shows another staple similar to that of Fig. 9 which is manufactured from flat metal stock and bent. Again the staple arms include wings 22 such that the width across these wings is significantly greater than the width of the staple back and staple legs.

The process by which these improved staples achieve greater areas of compression over the length of an

opening in body tissue is illustrated in Fig. 11. Fig. 11 shows a staple of the kind illustrated in Fig. 9 but the same principle applies to all the staples of Figs. 5 to 10. It can be seen that as the staple arms 10a move from their open position at 'A' to their closed position at 'B' tissue is compressed ahead of the wings 22 and this compression radiates over a much greater length of the slit or opening 16 than would be the case if the wings were not attached to the staple arms.

The invention is not limited to the embodiments described herein which may be modified or varied without departing from the scope of the invention.

Claims

1. A surgical staple comprising a base and a pair of substantially parallel legs projecting substantially perpendicularly from opposite ends of the base respectively, the base comprising a central portion ("back") and two outer portions ("arms") respectively on opposite sides of the back which in use of the staple are bent through approximately 90^0 relative to the back, the arms having a maximum width, in a direction normal to the plane containing the legs, greater than the width of the back.

2. A surgical staple as claimed in claim 1, wherein the arms comprise substantially flat portions of the base.

3. A surgical staple as claimed in claim 2, wherein the flat portions are formed by deformation of the base of an originally round wire staple.

4. A surgical staple as claimed in claim 2, wherein the flat portions are plates attached to a round wire staple.

5. A surgical staple as claimed in claim 2, wherein the staple is cut from flat metal stock and bent.

6. A surgical staple as claimed in claim 1, wherein the arms comprise portions of the base bent out of alignment with the back.

7. A surgical staple as claimed in claim 6, wherein the bent portions are sinusoidal.

8. A surgical staple as claimed in claim 6, wherein the arms are divided and opposite divisions bent in opposite directions

9. A surgical staple as claimed in any preceding claim, wherein the legs also have a greater width than the back of the staple.

Abstract

(Fig. 5)

A generally U-shaped surgical staple comprises a base and a pair of substantially parallel legs 12 extending substantially perpendicularly from opposite ends of the base respectively. The base 10 comprises a central portion (back) 10b and two outer portions (arms) 10a respectively on opposite sides of the back which in use of the staple are bent through approximately 90^0 relative to the back. To effect a greater compression of the stapled tissue the arms 10a have a greater height, in a plane normal to the legs 12, than the back 10a.

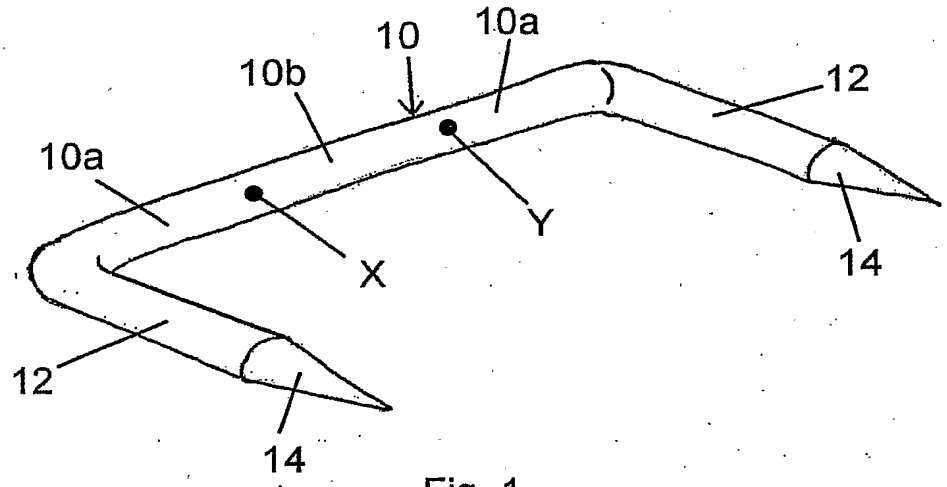
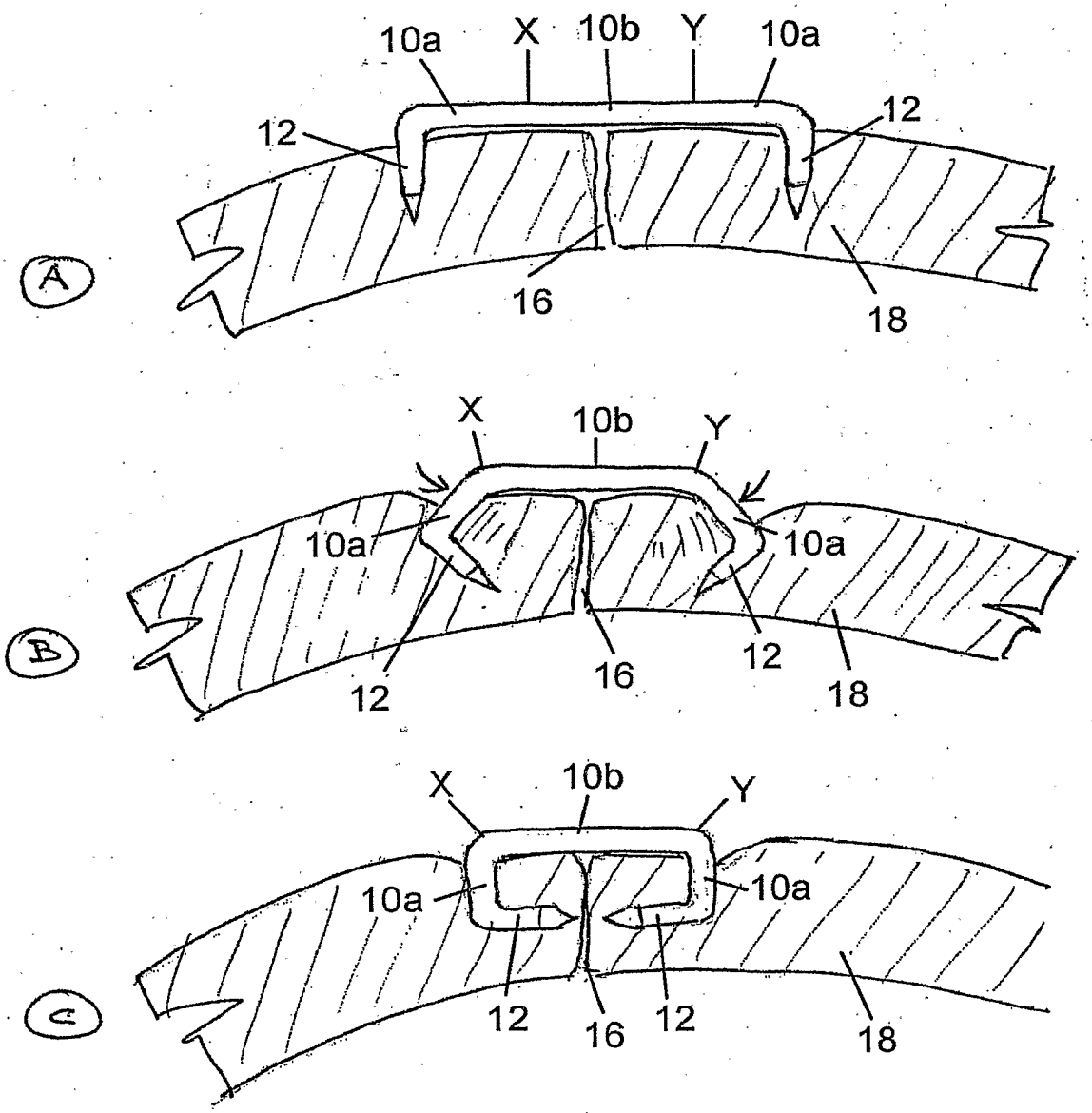

10
10a
10b
12
10a
Y
X
14
12
14

Fig. 1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B
X
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Y
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16
12
18

Fig. 2

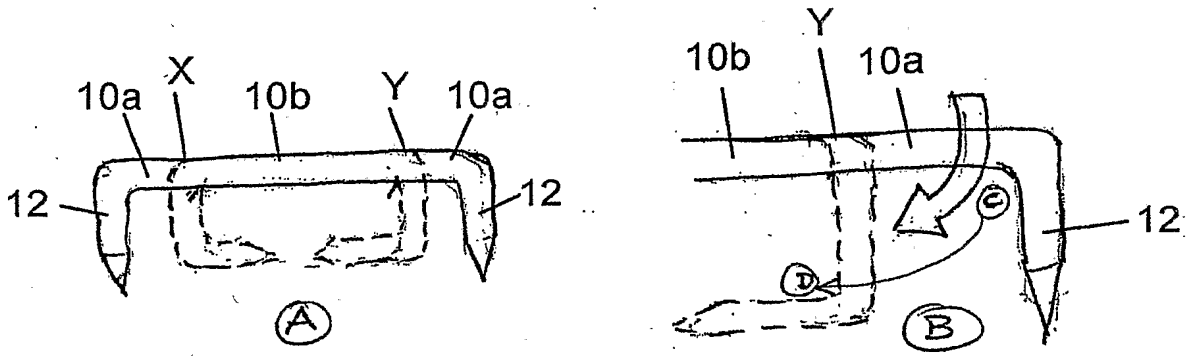

Fig. 3

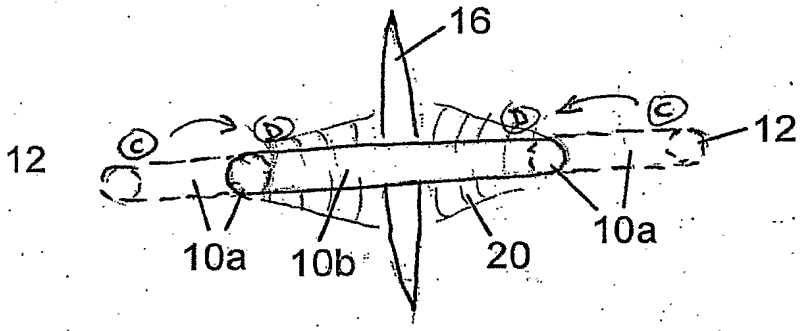

Fig. 4

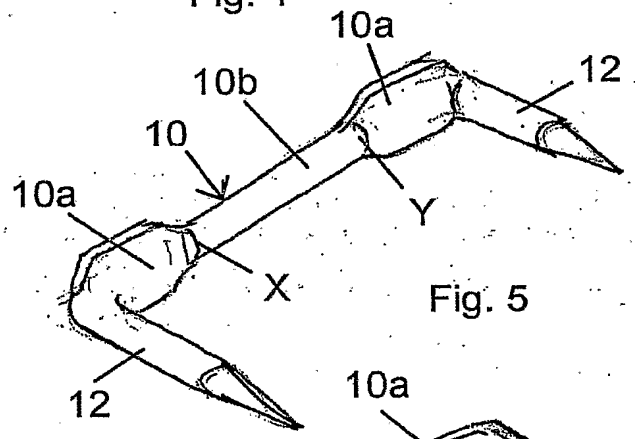

Fig. 5

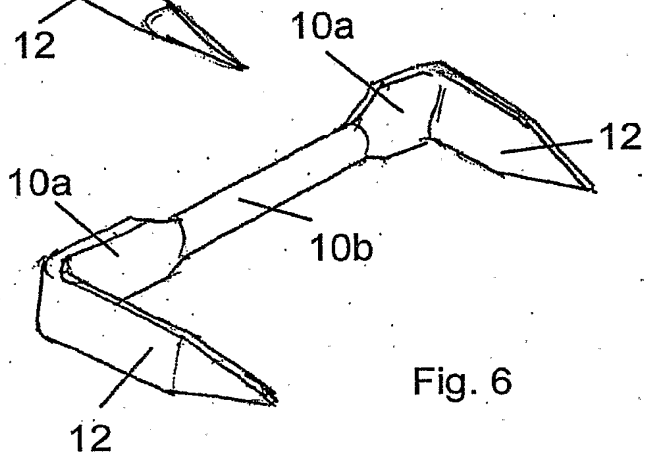

Fig. 6

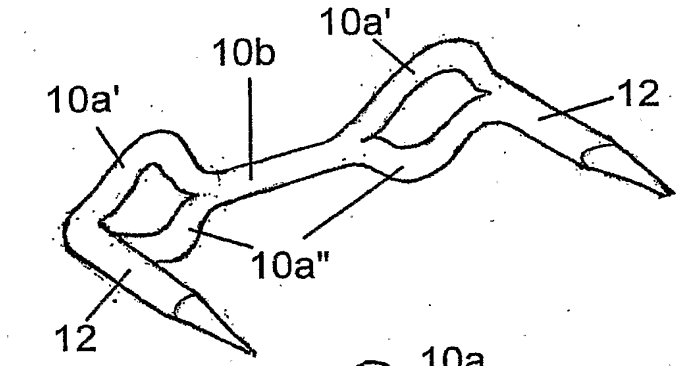

Fig. 7

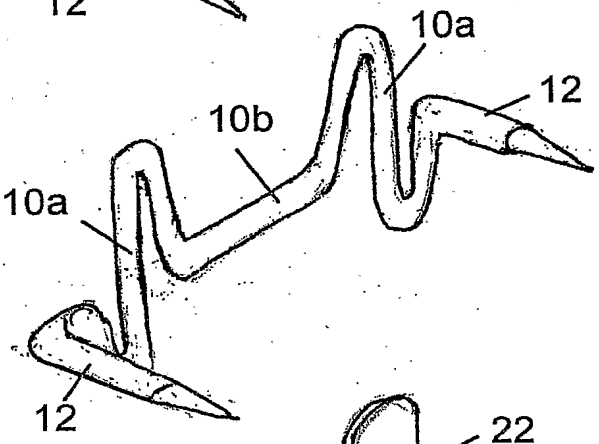

Fig. 8

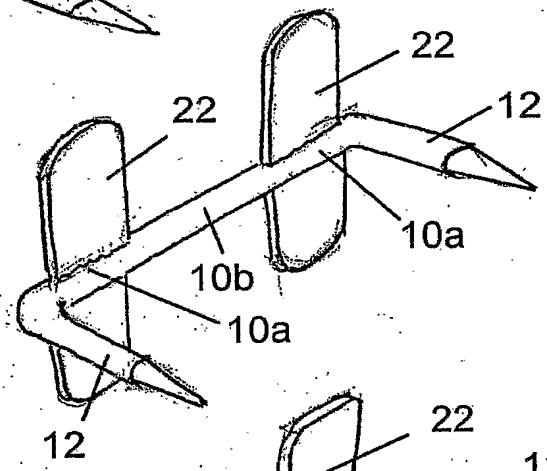

Fig. 9

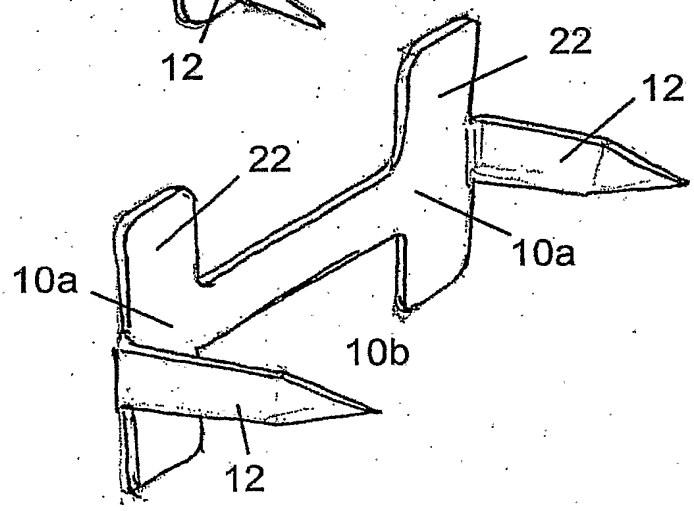

Fig. 10

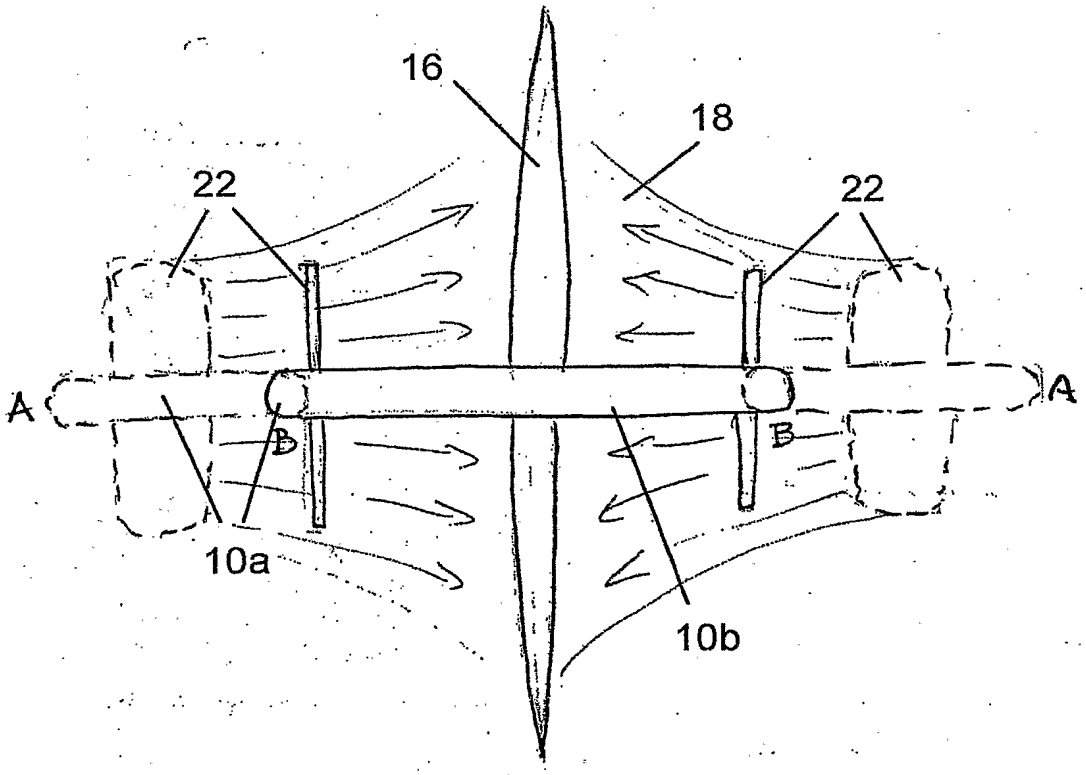

Fig. 11